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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,557	06/20/2003	Sebastian Vogt	100727-55/Heraeus 407-KGB	6050
27384	7590	02/16/2006	EXAMINER SILVERMAN, ERIC E	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/600,557

Applicant(s)

VOGT ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8-4-05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

Receipt of Information Disclosure Statement, filed 8-4-2005 is acknowledged.

Claims 1 – 8 are pending in this action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "retarding" in claims 1 – 8 is a relative term which renders the claim indefinite. The term "retarding" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since there is no baseline for comparison, it is impossible for Examiner to evaluate whether or not the release has been "retarded" as required by instant claims. Clarification is requested.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Franz et al., US 5,797,873.

Franz teaches processes for preparing bone cements comprising active compounds and bone replacement materials, wherein the active compound is dissolved

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in an organic solvent (abstract). The bone cements are based on acrylate/methacrylate esters (col. 3, lines 20 – 25), and the active ingredients of instant claims, Teicoplanin, gentamicin, clindamycin, and vancomycin are suggested as possible preferred components (paragraph bridging col. 3 and 4). These bone cements are used as pastes, for implantation of prostheses, and are molded into shaped articles, which can be provided in prefabricated form (col. 6, lines 5 – 14). Customary additives, such as calcium phosphate, hydroxyapatite, tricalcium phosphate, and sodium bicarbonate are taught to be added to modify the release rate (col. 4, line 53 – col. 5, line 19). To the extent that “retarding active ingredient release” is a structural limitation of the claims, the artisan would understand that mixing an active agent with any excipient will retard the release rate somewhat in comparison with administration of the active agent without any excipients.

Franz does not require all of the ingredients recited by instant claims, although Franz does suggest the use of these ingredients.

The artisan would therefore be motivated by the suggestions of Franz to use these ingredients. For instance, the artisan would be motivated to use hydroxyapatite, calcium phosphate, and similar excipients since Franz teaches that doing so would allow the artisan to modify the release rate. Franz also teaches that it is well known in the art to be desirable to delay the release of active agents in shaped agents made of bone cements (col. 2, lines 3 – 13). Accordingly, the artisan would find it obvious to make shaped articles with delayed release of active agents, since Franz teaches that this is customary in the art. The artisan would be motivated to do so since Franz

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teaches that this is a desirable feature. Franz teaches what excipients can be used for this purpose, so the artisan would enjoy a reasonable expectation of success.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franz in view of Pietsch, US 4,588,583.

The teachings of Franz are discussed above. Franz does not teach use of organic compounds such as lactides.

Pietsch teaches surgical material bone cements. Pietsch further teaches that adding certain liquids has the function of giving the bone cement a creamy consistency during the pasting phase and of reducing the viscosity (col. 3, lines 1 – 4). Pietsch further motivates the use of lactic acid as a liquid material because lactic acid gives the cement mixture a marked tackiness in the plastic state, which the artisan would recognize is useful for molding the mixture into a shaped article, as taught by Franz. As such, the artisan would have a reasonable expectation of success. The expected result would be a bone cement that is tacky during the drying phase, which is easier to mold into a shaped article.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franz in view of Pratt et al., US 4,283,799.

The teachings of Franz are discussed above.

Pratt teaches that during a process of implanting a bone prosthesis, it is preferable to coat the bone and the implant with a bone cement, since doing so

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increases the mechanical strength of the joint and prevents dislocation of the implant during surgery (col. 3 line 60 – col. 5, line 5).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to coat an implant, specifically a bone prosthesis, with the bone cement of Franz. The motivation to do so comes from Pratt, who teaches that this can increase mechanical strength of the joint and prevent dislocation of the implant during surgery. Since Pratt teaches how to do this, the artisan would enjoy a reasonable expectation of success. The expected result would be a bone implant that has greater mechanical strength and is not dislocated during surgery.

### ***Conclusion***

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

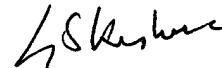
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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